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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,858	GISH ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) *13-55 and 68-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 56-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/15/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *05/23/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S-od

DETAILED ACTION

Applicant's election without traverse of group A, claims 1-12, 52-67, SEQ ID NO:41 in the reply filed on 07/16/04 and 03/14/05 is acknowledged.

Claims 52-55 are however are withdrawn from examination, because they are drawn to non-elected inventions, i.e. a method for detecting a prostate cancer-associated transcript, comprising detecting a plurality of polynucleotides shown in Tables 1-16 (see interview Summary with Viola Kung on 05/23/05).

Claims 1-70 are pending in the instant application and Claims 13-55, 68-70 have been withdrawn from further consideration by the Examiner under 37 CFR 1.142(b) as being drawn to non-elected invention.

Accordingly, Claims 1-12, 56-67, SEQ ID NO:41 are currently under prosecution.

OBJECTION

1. Claims 1-12, 56-67 are objected to for the use of the language "associated" in claims 1, 56. It is not clear what type of association is referred to.

2. Claims 1-12, 56-67 are objected to for the use of the language " a sequence as shown in Tables 1-16" in claims 1, 7, 56, 62, which encompass non-elected inventions.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH

Claims 1-12, 56-67 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

1) The detecting step after the contacting step in claim 1.

2) The quantitating step after the contacting step in claim 56.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

Claims 1-12, 56-67 are rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification.

Claims 1-12, 56-67 are drawn to:

A method for detecting or quantitating a prostate cancer-associated transcript in a cell from a patient, comprising contacting a biological sample from the patient with a polynucleotide "that selectively hybridizes" to a sequence at least "80% or 95% identical" to a sequence in Tables 1-16 (SEQ ID NO:41).

The specification discloses that "selectively hybridizes to" refers to the binding, duplexing or hybridizing of a molecule only to a particular nucleotide sequence that is

determinative of the presence of the nucleotide sequence, in a heterogeneous population of nucleic acids and other biologics (p. 22, lines 4-7).

It is noted that "a sequence at least "80% or 95% identical" to SEQ ID NO:41 encompasses variants of SEQ ID NO:41, with unknown structure and function, provided they are 80% or 95% identical to SEQ ID NO:41.

The claims 1-12, 56-57 encompass a method for detecting or quantitating a prostate cancer-associated transcript in a cell from a patient, comprising contacting a biological sample from the patient with a polynucleotide of "unknown structure and function", provided it hybridizes to "a variant of SEQ ID NO:41" via a common fragment with SEQ ID NO:41.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that □[a] written description of an invention involving a chemical genus, like a description of a chemical species, □requires a precise definition, such as by structure, formula, [or] chemical name,□ of the claimed subject matter sufficient to distinguish it from other materials.□ Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as □vertebrate insulin cDNA□ or □mammalian insulin cDNA□ without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by

> function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement" can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying

characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of "a polynucleotide that selectively hybridizes to a sequence at least 80% or 90% identical" to SEQ ID NO:41, as shown in the example of Lilly by structurally describing a representative number of the hybridizing polynucleotides and of sequences at least " 80% or 90% identical" to SEQ ID NO:41, or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, as shown in the example of Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe "a polynucleotide that selectively hybridizes to a sequence at least 80% or 90% identical" to SEQ ID NO:41 in a manner that satisfies either the standards as shown in the example of Lilly or Enzo. The

specification does not provide the complete structure of any "a polynucleotide that selectively hybridizes to a sequence at least 80% or 90% identical" to SEQ ID NO:41, other than SEQ ID NO:41, nor any physical or chemical characteristics of the transcytosis receptor nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses SEQ ID NO:41, this does not provide a description of "a polynucleotide that selectively hybridizes to a sequence at least 80% or 90% identical" to SEQ ID NO:41, that would satisfy the standard as shown in the example of Enzo.

The specification also fails to describe "a polynucleotide that selectively hybridizes to a sequence at least 80% or 90% identical" to SEQ ID NO:41 by the example in Lilly. The specification describes only a single polynucleotide of SEQ ID NO:41. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of the "a polynucleotide that selectively hybridizes to a sequence at least 80% or 90% identical" to SEQ ID NO:41, that is required to practice the claimed invention. Since the specification fails to adequately describe the product, it also fails to adequately describe the claimed method using said product.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT

Claims 1-12, 56-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-12, 56-67 are drawn to:

A method for detecting or quantitating a prostate cancer-associated transcript in a cell from a patient, comprising contacting "a biological sample" from the patient with a polynucleotide "that selectively hybridizes" to a sequence at least "80% or 95% identical" to a sequence in Tables 1-16 (SEQ ID NO:41). The patient is undergoing a therapeutic regimen to treat prostate cancer, or is suspected of having prostate cancer or metastatic protate cancer.

A. Claims 1-12, 56-67 are rejected under 112, first paragraph, because one cannot predict that SEQ ID NO:41 is overexpressed in prostate tumor tissue as compared to normal prostate tissue, and thus one would not know how to use the claimed method.

In the reply of 03/14/05, Applicant asserts that the unigene identifier HS.139336 corresponds to human ATP-binding cassette, subfamily C, member 4, and is set forth in SEQ ID NO:41 (NM-005845) in Table 16 (which was by typographic error labeled as Table 11 on page 302) on page 316 of the specification. Applicant asserts that SEQ ID NO:41 is identified as Hs.139336 in Table 15, at page 297, line 40. Applicant asserts

that Hs.139336 is a gene that is differentially expressed as shown in Tables 3, 4, 5, 6 and 7.

The specification discloses that Hs.139336 (or AF071202) is a gene that is differentially expressed in prostate tumor tissue compared to normal prostate tissue, using Affymetrix/Eos Hu02 Genechip array (Table 4, p. 138, line 50 and Table 3 on page 121). The specification discloses that RNAs from each prostate tumor are isolated and individual mRNA species is quantified using a custom Affymetrix GeneChip oligonucleotide microarrays, with probes to interrogate approximately 35,000 unique mRNA transcripts.

It is noted however that the submitted specification seems to end at page 295, and that tables 15 and 16, although recited in the claims, are not included in the specification.

Thus it is not clear whether SEQ ID NO:41 is the same as Hs.139336 (or AF071202) a human ATP-binding cassette, shown in Tables 3, 4, 5, 6 and 7, and is differentially expressed in prostate tumor tissue compared to normal prostate tissue.

Further, even if SEQ ID NO:41 is the same as Hs.139336 (or AF071202), one cannot extrapolate the teaching in the specification to the enablement of the claims, because in the absence of concrete objective evidence, one cannot predict that SEQ ID NO:41 is differentially expressed in prostate tumor tissue compared to normal prostate tissue, especially in view that only about 35,000 mRNAs transcripts are used in a microarray for quantifying SEQ ID NO:41.

One cannot predict that the screened 35,000 mRNAs transcripts are representative of all mRNAs present in a cell, and consequently, one cannot predict that SEQ ID NO:41 is differentially expressed in prostate tumor tissue compared to normal prostate tissue. A complete cDNA library is one that contains at least one cDNA clone representing each mRNA in a cell, and that there are about 34,000 different types of mRNAs in a mammalian cells and about 500,000 mRNA molecules per cell, as taught in a commonly used text book by Ausubel et al, eds, 1987 (Current protocols in molecular biology, John Wiley & Sons, New York, p. 5.8.1, under Production of a cDNA library). Ausubel et al further teach that if the number of molecules of the rarest mRNA in a cell is 8, the calculated number of clones that should be screened to achieve a 99% probability that a cDNA will exist in the library is 324,000. Similarly, in another commonly used text book by Sambrook et al, eds, 1989 (Molecular cloning, a Laboratory manuall, 2nd ed, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY, p.8.3-8.7) Sambrook et al teach that a typical mammalian cell contains between 10,000 and 30,000 different mRNA sequences. Sambrook et al further teach that for low abundance mRNAs, i.e. 14 copies/cell, although the minimum clones required to obtain representation of mRNAs of this class is 37,000, but because of preferential cloning of certain sequences, a much larger number of recombinants must be obtained to increase the chances that any given clone will be represented in the library, i. e., about 170,000 clones (p.8.5 last paragraph, bridging p.8.7). Sambrook et al also teach that unfortunately, many mRNAs of interest are present at even lower level, i.e. 1 molecule/cell is not unusual.

Thus based on the teaching in the art, it is clear that one cannot predict that the screened 35,000 mRNA transcripts would be representative of all mRNAs present in a cell. The identification of SEQ ID NO:41 in the selected, incomplete pool of mRNAs transcripts appears to be a serendipitous event. The fact that the claimed polynucleotide is not expressed in one pool of mRNAs transcripts or is expressed in another appears to be an artifact of the analytical system and cannot be extrapolated to a prediction of whether that molecule is expressed in the tissue "represented" by the pool of mRNAs transcripts.

Neither the specification nor any art of record teaches what SEQ ID NO:41 is, what it does do; they do not teach a relationship to any specific diseases or establish any involvement in the etiology of any specific diseases.

Further, the claims read on a method for detecting or quantitating "any" prostate cancer-associated transcript, by selectively hybridizing with SEQ ID NO:41. One would not expect that any prostate cancer-associated transcript would be detected by the claimed method, due to structural differences.

In view of the above, one would not know how to use the claimed method, and it would be undue experimentation for one of skill in the art to practice the claimed invention.

B. If Applicant could overcome the above 112, first paragraph, claims 1-12, 56-67 are still rejected under 112, first paragraph, because the claims 1-12, 56-57 encompass a method for detecting or quantitating a prostate cancer-associated transcript in a cell from a patient, comprising contacting a biological

sample from the patient with a polynucleotide of "unknown structure and function", provided it hybridizes to "a variant of SEQ ID NO:41" via a common fragment with SEQ ID NO:41.

The specification discloses that "selectively hybridizes to" refers to the binding, duplexing or hybridizing of a molecule only to a particular nucleotide sequence that is determinative of the presence of the nucleotide sequence, in a heterogeneous population of nucleic acids and other biologics (p. 22, lines 4-7).

It is noted that the definition is not limiting. The claimed probe would hybridize unrelated sequences which are determinative of the presence of said unrelated nucleotide sequences in a heterogeneous population of nucleic acids and other biologics.

Further, the scope of the claims 1-12, 56-67 includes detecting numerous structural variants of SEQ ID NO:41.

Even if SEQ ID NO:41 is differentially expressed in prostate tumor tissue as compared to normal prostate tissue, one cannot extrapolate the teaching in the specification to the scope of the claims because one cannot predict that the variants of SEQ ID NO:41 would have the same expression pattern as that of SEQ ID NO:41, and would be useful for detecting prostate cancer or metastatic prostate cancer. It is well known in the art that it is not necessary that variants are expressed in the same pattern as the wild type parent sequence. For example, Schmid S et al, 2001, J comparative Neurology, 430(2): 160-71, teach that the variants flip/flop of the gene GluR are expressed at higher levels in neurons in the auditory brainstem, as compared to the wild

type GluR-A and GluR-B, and that neurons in the central nucleus of the inferior collicullus express high levels of GluR-B flip but only low levels of the other receptor subunits. Conner et al, 1996, Mol Brain Res, 42: 1-17, teach that full length trkB is found the hippocampus in patients with Alzheimer's disease, but not in hippocampi of either normal age-matched individual or patients with Huntington's disease, and that truncated trkB is found in senile plaques in hippocampus and temporal lobe in both patients with Alzheimer's disease and Huntington's disease, but not in normal brains of aged-matched individuals (page 8, item 3.1.2).

In view of the above, it would be undue experimentation for one of skill in the art to practice the claimed invention.

C. If Applicant could overcome the above 112, first paragraph, claims 1-12, 56-67 are still rejected under 112, first paragraph, because the claims 1-12, 56-57 encompass a method for detecting or quantitating a prostate cancer-associated transcript in a cell from a patient, using "any biological sample from the patient, which could be any tissues, or any bodily fluids to which the prostate cancer cells have metastasized".

It is noted that the specification discloses that Hs.139336 is prostate specific and is not detected in other normal tissues (Table 3, p.121, and 129, line 45).

Even if the claimed polypeptide of SEQ ID NO:41 is the same as Hs.139336 and is overexpressed in a prostate cancer tissue as compared to normal prostate tissue, it is unpredictable that one could detect the claimed polypeptide by detecting any biological sample, or any tissues or which the prostate cancer cells have metastasized. It is

unpredictable that metastasized prostate cells still express the claimed sequence, because expression of a sequence could be lost during the progression toward metastasis. For example, Kibel, AS et al, 2000, J urol, 164(1): 192-6 teach that gene expression in the chromosomal region 12p12-13 is different in primary and metastatic prostate cancer cells, and that inactivation in the chromosome region 12p12-13 occurs prior to metastasis. Zhau, HE, 1994, J Cell Biochem, Suppl 19: 208-216, teach expression of various biomarkers associated with prostate cancer progression. Zhau et al teach that in prostate cancer, PC-3N35 subclones which are cloned from primary and metastatic sites (lymph node, kidney and bone), show difference in the levels of protein expression of various markers, such as c-erbB, vimentin, ICAM-1, cytokeratin, collagen IV between the parental PC-3N35 clone and its metastatic subclones (p.209 and table 1) and that the subline derived from the metastatic site lymph node has a 12p:17q translocation, whereas the bone-derived subline contains an isochromosome 7q (p.211, first column, first paragraph). Cheung S T et al, 2002, Cancer Research, 62(16): 4711-21, teach that from 63 metastatic clones, 39 known genes and 24 express sequence tags are down-regulated, whereas in other 27 metastatic clones 14 known genes and 13 express sequence tags are up-regulated. Ren, C et al, 1998, Cancer Res, 58(6): 1285-90, teach a loss of expression of lysyl oxidase mRNA during progression to metastasis. Gingrich, JR et al, 1996, Cancer res, 56(18): 4096-4102 teach a loss of normal E-cadherin expression as primary tumors become less differentiated and metastasize.

Thus in view of the above, one would not have expected that the claimed sequences are useful for diagnostic information about the presence in a subject of an invasive prostate tumor.

In view of the above, it would be undue experimentation for one of skill in the art to practice the claimed method.

REJECTION UNDER 35 USC 102(e)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant

for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-12, 56-67 are drawn to:

1) A method for detecting or quantitating a prostate cancer-associated transcript in a cell from a patient, comprising contacting a biological sample from the patient with a polynucleotide "that selectively hybridizes" to a sequence at least "80% or 95% identical" to a sequence in Tables 1-16 (SEQ ID NO:41). Said method could further comprise amplifying nucleic acids before the step of contacting the biological sample with the polynucleotide (claims 1-2, 6, 56-57, 61).

2) The above method of claim 1 or 56, wherein the biological sample is a tissue sample, or comprises isolated nucleic acids, wherein the isolated nucleic acids could be mRNA (claims 3-5, 58-60).

3) The above method of claim 1 or 56, wherein the polynucleotide is labeled, wherein the label could b a fluorescent label (claims 8-9, 63-64).

4) The above method of claim 1 or 56, wherein the polynucleotide is immobilized on a solid surface.

5) The above method of claim 1 or 56, wherein the patient is undergoing a therapeutic regimen to treat prostate cancer, or is suspected of having prostate cancer or metastatic prostate cancer (claims 11-12, 66-67).

1. Claims 1-5, 7-12, 56-60, 62-67 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 01/60860A2.

WO 01/60860A2 teaches a prostate cancer marker of 424 nucleotides in length. The nucleotides 46-381 of said marker is 100% similar to SEQ ID NO:41, from nucleotide 532 to 867, as shown by MPSRCH sequence similarity search report (MPSRCH search report, 2005, us-09-976-858-41.oli.rng, page 2).

WO 01/60860A2 teaches diagnosing whether a patient is afflicted with or has higher than normal risk of developing prostate cancer, or whether prostate cancer has metastasized, comprising detecting a significant difference between the level of expression of the marker in a patient sample, as compared to normal level (p.3-4, under Summary of the invention, p.6, lines 24-30, bridging p.7)). WO 01/60860A2 teaches that the method may further be of particular use in monitoring the efficacy of treatment of a prostate cancer patient (p.4, lines 22-24).

WO 01/60860A2 teaches that the sample comprises cells from a prostate tissue sample (p.3, lines 26-28). WO 01/60860A2 teaches that the method can be used to detect isolated mRNA, cDNA or genomic DNA in northern or southern hybridization or polymerase chain reaction (p.80, last paragraph, bridging p.81, p.84, lines 16-18).

WO 01/60860A2 teaches diagnostic assays, wherein the marker or probe is anchored to a solid phase support, such as in Affymetrix gene chip array (p.84, lines 30-31). WO 01/60860A2 teaches that the marker can be labeled (p.82, third paragraph) and is differentially detectable using radioactivity, different chromophores or fluorophores (p.19, lines 6-7).

The method taught by WO 01/60860A2 seems to be the same as the claimed method, since the sequence taught by WO 01/60860A2 would selectively hybridize to SEQ ID NO:41.

2. Claims 1-2, 7-8, 12, 56-57, 61, 62-63 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,329,505 B1.

US 6,329,505 B1 teaches SEQ ID NO:535, a prostate cancer marker of 6082 nucleotides in length. The nucleotides 186-4162 of said marker is 100% similar to full length SEQ ID NO:41, from nucleotide 1 to nucleotide 3978, as shown by MPSRCH sequence similarity search report (MPSRCH search report, 2005, us-09-976-858-41.rni, pages 3-5).

US 6,329,505 B1 teaches that SEQ ID NO:535 is a first full length cDNA sequence of the clone P510S (column 17, lines 23-24), which the same as the known PSA gene (Table 1 on column 60).

US 6,329,505 B1 teaches methods for detecting prostate cancer, and that polynucleotide primers and probes may be used to detect the level of mRNA of the prostate tumor sequence in a biological sample (column 36, last paragraph, bridging column 37, column 40, lines 35-37). US 6,329,505 B1 teaches that the prostate specific

cDNA could be amplified by PCR, for use in hybridization assay to detect the presence of the polynucleotide (column 40, lines 35-49). US 6,329,505 B1 teaches that for hybridization, a partial sequence may be labeled (column 20, lines 17-18).

The method taught by US 6,329,505 B1 seems to be the same as the claimed method, because detecting the sequence taught by US 6,329,505 B1 would also detect SEQ ID NO:41 of the claimed method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

May 20, 2005